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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,989	11/13/2001	Michael Brown	108172-00072	6030

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,989	BROWN ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

1. This action is in response to the Amendment and Response filed May 27, 2003. Claim 1 has been amended and claim 2 has been added. Claims 1-2 are now pending and under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

THE FOLLOWING ARE NEW GROUNDS OF OBJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

3. Claim 2 is objected to as being dependent upon a rejected base claim. The claim encompasses allowable subject matter, as discussed further below; however, the current form of the claim is improper.

Claim Rejections - 35 USC § 112

4. In view of the amendment of claim 1 such that the claim is limited to human subjects and to human angiotensin converting enzyme gene (ACE), the rejections of the claim under 35 U.S.C. 112 first paragraph and 35 U.S.C. 112 second paragraph are withdrawn.

Claim Rejections - 35 USC § 102

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hagberg et al (WO 99/45383 A1 [9/1999]), for the reasons set forth below and in the Office action of February 25, 2003.

The response traverses the rejection on the following grounds. The response argues that Hagberg et al cannot anticipate the claimed invention because Hagberg et al do not teach every aspect of the invention. Applicant notes that "the claim preamble supplies a limitation, that of increasing sodium excretion" and that "Claim 1 ends with the requirement that the limited exercise training be for a period of time sufficient to increase sodium excretion levels," whereas "Hagberg does not even discuss sodium excretion levels." The response further argues that no evidence has been provided "that the use of the Hagberg process would necessarily increase the sodium excretion levels of the subject" and that "the time period sufficient for reducing blood pressure would also be sufficient for increasing sodium excretion." The response cites MPEP 2112, stating that section 2112 "requires that an inherency rejection be supported by proof that the alleged inherent property would necessarily flow from the teachings of the cited reference," and that section 2112 states "that the 'mere fact that a certain thing may result from a given set of circumstances is not sufficient' to support an inherency rejection."

These arguments have been thoroughly considered but are not persuasive for the following reasons. First, it is acknowledged that the Hagberg et al reference does not discuss sodium excretion levels, and further that a reference must teach every

element of a claim in order to anticipate that claim. However, an anticipatory reference is not required to teach each element of a claim expressly – a reference that describes each element of a claimed invention “expressly or inherently” is anticipatory (see, e.g., MPEP 2131). It is noted that the rejection set forth in the Office action of February 25, 2003 did not assert that Hagberg et al taught each element of the claimed invention expressly. Rather, as discussed in that Office action, instant claim 1 encompasses methods in which both “identifying” and “engaging” steps disclosed by Hagberg et al are performed, and the performance of the methods of Hagberg et al would inherently result in increasing sodium excretion levels in a hypertensive subject. Whether or not the Hagberg et al reference states or recites the fact that sodium excretion levels increase as a result of the performance of Hagberg et al’s method steps does not alter the properties of the steps performed, or the inherently resulting effects of the performance of those steps in a subject. Regarding Applicant’s argument that evidence that Hagberg et al’s process would increase sodium excretion has not been provided, it is noted that Applicant’s own specification provides evidence that performance of the steps taught by the Hagberg et al reference inherently result in increased sodium excretion.

Specifically, the specification teaches and exemplifies the fact that the same number of “single courses of exercise” performed over an exercise period encompassed by the exercise period defined by Hagberg et al result in increased sodium excretion. Further, with respect to Applicant’s argument that evidence is lacking that “the time period sufficient for reducing blood pressure would also be sufficient for increasing sodium excretion,” it is again noted that the time period for which exercise is performed is one

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element of the definition of "moderate exercise" provided by Hagberg et al and "limited exercise" provided in the instant specification (see the Office action of February 25, 2003). Hagberg et al teach a period that "may be from about 5-50 days, preferably from about 5-30 days, 5-20 days, or 5-15 days," while the specification teaches a period that is "preferably 5-30 days, most preferred about 5-20 days, most preferred about 5-12 days." Accordingly, it is clear from the definitions provided by the specification and by Hagberg et al that the instant claim step of "engaging the human subject in limited exercise training for a period of time sufficient to increase sodium excretion levels" encompasses periods of time disclosed by Hagberg et al. For example, the "most preferred" period disclosed in the specification (5-12 days) clearly falls within the narrowest range of time disclosed by Hagberg et al (5-15 days), and the broadest range disclosed in the specification (5-30 days) similarly falls within the broadest range specifically disclosed by Hagberg et al (5-50 days). Accordingly, an argument that the instant claim requires performance of exercise for a period of time longer than that disclosed by Hagberg et al, and/or that the period of time taught by Hagberg et al may be insufficient to produce the result of increasing sodium excretion, is not persuasive. Even if the maximum "preferred" number of days disclosed in the specification (30 days) were required to accomplish increased sodium excretion, this duration of exercise is clearly taught by Hagberg et al (as are longer periods, up to 50 days).

Hagberg et al teach all the limitations recited in present claim 1, and therefore this rejection is maintained.

Double Patenting

6. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,399,306 B1, for the reasons set forth below and in the Office action of February 25, 2003.

The response traverses the rejection for the same reasons discussed in paragraph 5, above. Accordingly, the response to those arguments applies equally herein. It is again noted that performance of the steps of claim 8 of the '306 patent, and particularly the "moderate exercise training" required by claim 8, would inherently result in increasing sodium excretion levels in a hypertensive subject. Accordingly, Applicant's arguments are not persuasive.

Claim 8 of the '306 patent anticipates instant claim 1, and therefore this rejection is maintained.

Allowable Subject Matter

7. The prior art does not teach or suggest methods meeting the requirements of instant claim 2. That claim requires a step of "testing the sodium excretion levels of the human subject following the period of time sufficient to increase sodium excretion levels." The specification exemplifies the fact that performance of "identifying" and "engaging" steps meeting the requirements of the claims result in increased sodium excretion levels in hypertensive subjects. However, as the prior art does not disclose the fact that performance of such steps has this effect, the prior art does not provide motivation to perform an additional method step of testing sodium excretion levels "following the period of time sufficient to increase sodium excretion levels."

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection and/or objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

A handwritten signature in cursive script, reading "Diana B. Johannsen".

Diana B. Johannsen
August 6, 2003

A handwritten signature in cursive script, reading "Carla J. Myers".
**CARLA J. MYERS
PRIMARY EXAMINER**